

WHAT IS CLAIMED IS:

1. A kit of parts for the delivery of a stent within a body lumen comprising:

a) an elongated sheath having proximal and distal ends, an outer lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the outer lumen;

b) an elongated catheter to be disposed within the outer lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is to receive on the exterior thereof an expandable stent, an inner lumen which is to receive a guiding member therein and which extends between a first and second ports of the catheter; and

c) means to adjust the relative axial positions of the catheter and the sheath to expose the expandable member so that upon the expansion thereof an expandable stent disposed about the expandable member will thereby be expanded.

2. The stent delivery system kit of claim 1 including an expandable stent which is to be mounted on the exterior of the expandable member on the catheter.

3. The stent delivery system of claim 1, wherein the sheath has a wall with a slit therein extending between the first and second ports thereof.

4. The stent delivery system of claim 1, wherein the catheter has a wall with a slit therein

extending from the second port to a location proximal to the expandable member.

5. A system for the delivery of an expandable stent within a body lumen over a guiding member comprising:

5 a) an elongated sheath having proximal and distal ends, an outer lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the outer lumen;

10 b) an elongated catheter disposed within the outer lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is to receive on the exterior thereof an expandable stent, and an inner lumen which is to slidably receive a guiding member therein, said inner lumen extending between a first port in the distal end of the catheter and a second port spaced proximally from the distal end of the catheter, both of the ports being in fluid communication with said inner lumen of the catheter, said elongated catheter axially spaced from the outer lumen when said outer lumen overlies said catheter, so as to be substantially non-abutting with said outer lumen at said distal end of the catheter; and

20 c) means to adjust the relative axial positions of the catheter and sheath to expose the expandable member on the catheter.

25 6. The stent delivery system of claim 5, wherein the sheath has a wall with a slit therein extending between the first and second ports thereof.

7. The stent delivery system of claim 5, wherein the catheter has a wall with a slit therein extending from the second port to a location proximal to the expandable member.

8. The stent delivery system of claim 5, wherein the means to adjust the relative axial positions of the catheter and the sheath includes a manipulator comprising:

an elongated housing having proximal and distal ends and an interior chamber;

a cap which has a threaded passageway therethrough and which is rotatably mounted on an end of the elongated housing; and

a longitudinally movable drive member which has a threaded exterior, which is disposed at least partially within the interior chamber of the elongated housing and which has a distal end extending through a central passageway of the cap, rotation of the cap causing axial movement of the drive member.

9. The stent delivery system of claim 8, wherein the longitudinally movable drive member has a central passageway which receives the proximal end of the catheter.

10. The stent delivery system of claim 9, wherein the proximal end of the catheter is fixed to the manipulator housing.

11. The stent delivery system of claim 9, wherein the sheath is fixed to the distal end of the longitudinally movable drive member which extends out the distal end of the manipulator.

12. A method of delivering an expandable stent to a desired location within a patient's body lumen which has a guidewire disposed therein with a proximal end extending out of the patient, the method comprising:

a) providing an elongated sheath having proximal and distal ends, a first port in the distal end of said sheath and a second port spaced proximally from said distal end;

an elongated catheter disposed within said elongated sheath having proximal and distal ends, a first port in the distal end of said elongated catheter and a second port spaced proximally from said distal end of the elongated catheter, said catheter having an expandable member proximally adjacent to said distal end of the catheter and having mounted on the exterior thereof an expandable stent, said catheter having an inner lumen to slidably receive a guidewire therein, said guidewire extending between said first and second ports of the elongated catheter, with said first and second ports of the elongated sheath and first and second ports of the elongated catheter being in fluid communication;

b) adjusting the relative axial positions of the elongated sheath and the catheter so as to at least partially align said second port of the elongated sheath and proximal second port of the elongated catheter;

c) positioning said guidewire so that a portion of the guidewire extends through said second port of the elongated sheath and proximal second port of the elongated catheter;

d) advancing said sheath and catheter over the guidewire through the body lumen to the desired location therein;

e) adjusting the relative axial positions of said sheath with respect to said catheter to expose said expandable stent on said expandable member;

f) expanding said expandable member to thereby expand said stent mounted thereon at said desired location within the body lumen, after said expandable stent has been exposed;

g) contracting said expandable member on the catheter; and

h) withdrawing said catheter and sheath from said body lumen.

13. The method of claim 12, wherein the expandable member is a balloon and wherein inflation fluid is directed to the interior of the balloon to expand the balloon and thereby expand the stent mounted thereon.

14. The method of claim 12, wherein the expandable stent engages the wall defining the body lumen when said stent is expanded so as to maintain the patency thereof.

15. A system for delivery of an expandable stent within a body lumen comprising:

a longitudinally elongated catheter having a proximal end and a distal end,

a guidewire to be slidably received inside said catheter;

said catheter having a balloon portion at its distal end to expand said expandable stent;

an elongated outer lumen, having a proximal and a distal end, surrounding said catheter and to cover said expandable stent, said outer lumen axially spaced from said catheter at said distal end of the catheter, when said outer lumen

cat 50 232260

15

overlies said catheter, so as to be substantially non-abutting with said catheter at said distal end of the catheter;

means to adjust the relative axial positions of the outer lumen and the catheter to uncover said expandable stent.

16. The stent delivery system of claim 15, wherein said outer lumen has a longitudinally extending slit extending therein, to allow passage of said guidewire.

17. The stent delivery system of claim 15, wherein the means to adjust the relative axial positions of the outer lumen and catheter includes a manipulator comprising:

an elongated housing with proximal and distal ends and an interior chamber;

a cap with a threaded passageway therethrough and rotatably mounted on an end of the elongated housing; and

a longitudinally movable drive member having a threaded exterior, disposed at least partially within the interior chamber of the elongated housing and having a distal end extending through the central passageway of the cap;

whereby rotation of said cap causes axial movement of said drive member.

18. The stent delivery system of claim 17, wherein said longitudinally movable drive member has a central passageway operatively connected to said proximal end of said outer lumen.

604430" 604430"

5

10

15

19. The stent delivery catheter of claim 18, wherein said proximal end of the catheter is fixed to the manipulator housing.

20. The stent delivery catheter of claim 18, wherein the proximal end of said outer lumen is fixed to the distal end of the longitudinally movable drive member.

21. A kit of parts for the delivery of a stent within a body lumen comprising:

a) an elongated sheath having proximal and distal ends, a tapering portion proximal to said distal end, an outer lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the outer lumen;

b) an elongated catheter to be disposed within the outer lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is to receive on the exterior thereof an expandable stent, an inner lumen which is to receive a guiding member therein and which extends between a first and second ports of the catheter; and

c) an elastic cone having proximal and distal ends, having a small aperture in the distal end and a large aperture in the proximal end thereof, the large aperture of which is to receive the distal end of the elongated sheath;

d) means to adjust the relative axial positions of the catheter and the sheath to expose the expandable member so that upon the expansion thereof an expandable stent disposed

about the expandable member will thereby be expanded.

22. The stent delivery system kit of claim 21 including an expandable stent which is to be mounted on the exterior of the expandable member on the catheter.

23. The stent delivery system of claim 21, wherein the sheath has a wall with a slit therein extending between the first and second ports thereof.

24. The stent delivery system of claim 21, wherein the catheter has a wall with a slit therein extending from the second port to a location proximal to the expandable member.

25. A system for the delivery of an expandable stent within a body lumen over a guiding member comprising:

a) an elongated sheath having proximal and distal ends, a tapering portion proximal to said distal end, an outer lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the outer lumen;

b) an elongated catheter disposed within the outer lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is to receive on the exterior thereof an expandable stent, and an inner lumen which is to slidably receive a guiding member therein, said inner lumen extending between a first port in the distal end of the catheter and a second port spaced proximally from the distal end of the

664130" 23222200

5

10

15

20



catheter, both of the ports being in fluid communication with said inner lumen of the catheter, said elongated catheter axially spaced from the outer lumen when said outer lumen overlies said catheter, so as to be substantially non-abutting with said outer lumen at said distal end of the catheter; and

c) an elastic cone having proximal and distal ends, having a small aperture in the distal end and a large aperture in the proximal end thereof, the large aperture of which is to receive the distal end of the elongated sheath;

d) means to adjust the relative axial positions of the catheter and sheath to expose the expandable member on the catheter.

26. The stent delivery system of claim 25, wherein the sheath has a wall with a slit therein extending between the first and second ports thereof.

27. The stent delivery system of claim 25, wherein the catheter has a wall with a slit therein extending from the second port to a location proximal to the expandable member.

28. The stent delivery system of claim 25, wherein the means to adjust the relative axial positions of the catheter and the sheath includes a manipulator comprising:

an elongated housing having proximal and distal ends and an interior chamber;

a cap which has a threaded passageway therethrough and which is rotatably mounted on an end of the elongated housing; and

a longitudinally movable drive member which has a threaded exterior, which is disposed at least partially within the interior chamber of

001150 2322200

15

the elongated housing and which has a distal end extending through a central passageway of the cap, rotation of the cap causing axial movement of the drive member.

29. The stent delivery system of claim 28, wherein the longitudinally movable drive member has a central passageway which receives the proximal end of the catheter.

30. The stent delivery system of claim 29, wherein the proximal end of the catheter is fixed to the manipulator housing.

31. The stent delivery system of claim 29, wherein the sheath is fixed to the distal end of the longitudinally movable drive member which extends out the distal end of the manipulator.

32. A method of delivering an expandable stent to a desired location within a patient's body lumen which has a guidewire disposed therein with a proximal end extending out of the patient, the method comprising:

a) providing an elongated sheath having proximal and distal ends, a tapering portion proximal to said distal end, a first port in the distal end of said sheath and a second port spaced proximally from said distal end;

an elongated catheter disposed within said elongated sheath having proximal and distal ends, a first port in the distal end of said elongated catheter and a second port spaced proximally from said distal end of the elongated catheter, said catheter having an expandable member proximally adjacent to said distal end of the catheter and having mounted on the exterior

5

10

15

004450 232120

thereof an expandable stent, said catheter having an inner lumen to slidably receive a guidewire therein, said guidewire extending between said first and second ports of the elongated catheter, with said first and second ports of the elongated sheath and first and second ports of the elongated catheter being in fluid communication;

an elastic cone having proximal and distal ends, having a small aperture in the distal end and a large aperture in the proximal end thereof, the large aperture of which is the receive the distal end of the elongated sheath;

b) adjusting the relative axial positions of the elongated sheath and the catheter so as to at least partially align said second port of the elongated sheath and proximal second port of the elongated catheter;

c) positioning said guidewire so that a portion of the guidewire extends through said second port of the elongated sheath, the small aperture of the elastic cone and proximal second port of the elongated catheter;

d) advancing said sheath and catheter over the guidewire through the body lumen to the desired location therein;

e) adjusting the relative axial positions of said sheath with respect to said catheter to expose said expandable stent on said expandable member thereby disengaging said elastic cone from said sheath;

f) said elastic cone collapsing upon distal end of the catheter;

g) expanding said expandable member to thereby expand said stent mounted thereon at said desired location within the body lumen, after said expandable stent has been exposed;

i) withdrawing said catheter and sheath from said body lumen.

34. The method of claim 32, wherein the expandable stent engages the wall defining the body lumen when said stent is expanded so as to maintain the patency thereof.

a) an elongated sheath having proximal and distal ends, a tapering portion proximal to said distal end, a plurality of slits extending a short distance from said distal end, an outer lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the outer lumen;

b) an elongated catheter disposed within the outer lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is to receive on the exterior thereof an expandable stent, and an inner lumen which is to slidably receive a guiding member therein, said inner lumen extending between a first port in the distal end of the catheter and a second port spaced proximally from the distal end of the

25 catheter, both of the ports being in fluid  
communication with said inner lumen of the  
catheter, said elongated catheter axially spaced  
from the outer lumen when said outer lumen  
overlies said catheter, so as to be  
substantially non-abutting with said outer lumen  
at said distal end of the catheter; and

30 c) an elastic cone having proximal and  
distal ends, having a small aperture in the  
distal end and a large aperture in the proximal  
end thereof, the large aperture of which is the  
receive the distal end of the elongated sheath;

35 d) means to adjust the relative axial  
positions of the catheter and sheath to expose  
the expandable member on the catheter.

664950-SECRET

Add A6